CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-456/458

APPROVAL LETTER

ANDA 75-456 (Carpuject)
75-458 (Vials, 1 mL & 2 mL)

AUG 2 2 2000

Abbott Laboratories
Attention: Jessie Y. Lee
200 Abbott Park Road; D-389, Bldg. AP30
Abbott Park, IL 60064-6157

Dear Madam:

This is in reference to your abbreviated new drug applications dated September 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Enalaprilat Injection, 1.25 mg/mL.

Reference is made the Tentative Approval letters issued by this office on October 29, 1999 and January 24, 2000, and to your amendments to each application dated June 20, 2000.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Enalaprilat Injection, 1.25 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug [Vasotec® I.V. Injection, 1.25 mg/mL, of Merck Research Laboratories].

Under section 506A of the Act, certain changes in the conditions described in these abbreviated applications require approved supplemental applications before the change may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and

Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler 8/22/00
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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